IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA, ex rel. STEPHEN MCMULLEN,	)	No. 3:12-cv-00501
Plaintiff,	)	Judge Campbell
v.	)	
ASCENSION HEALTH,	)	Magistrate Judge Griffin
Defendant.	)	Oral Argument Requested

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS RELATOR'S COMPLAINT FOR DAMAGES

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Defendant Ascension Health ("Ascension") respectfully submits this Memorandum of Law in Support of its Motion to Dismiss Relator's Complaint for Damages Under the False Claims Act, 31 U.S.C. § 3729, *et. seq.* (the "Complaint") pursuant to Federal Rules of Civil Procedure 8(a), 9(b), and 12(b)(6) (the "Motion"). For the reasons set forth more fully below, the Court should grant the Motion and dismiss the Complaint with prejudice.

PRELIMINARY STATEMENT

Stephen McMullen, a serial relator, has sued the Catholic nonprofit corporation Ascension, which serves as the "parent" corporation of numerous Catholic charity corporations that in turn own or operate licensed hospitals in several states. Boiled down, McMullen accuses Ascension of failing to adhere to legally non-binding local Medicare contractors' guidance in submitting claims for Medicare reimbursement for noninvasive diagnostic tests performed in over 500 facilities. But, as a matter of public record, Ascension does not and legally cannot submit any claims to Medicare. It is neither an operator of a hospital, nor a provider authorized to seek reimbursement from Medicare for health care services provided to patients.

Aside from conclusory recitations of the statutory framework of the False Claims Act ("FCA"), McMullen offers few facts to support his accusations of fraud by Ascension. As factual support for his allegations, McMullen relies upon his eight-month employment at a single hospital in Nashville, Tennessee – Baptist Hospital. The Complaint offers no facts suggesting that Ascension submitted any claims to Medicare; nor does it offer facts showing that Ascension caused Baptist Hospital, or any other hospital, to submit any claims, much less any false claims to Medicare. McMullen speculates that Baptist Hospital submitted false claims for the tests in question, but does not identify a single claim submitted to Medicare by Baptist Hospital.

Similarly, McMullen alleges violations of other FCA provisions but no specific false record or statement is identified in the Complaint. And no facts demonstrating the existence of conspirators, much less submission of false claims by conspirators are found in the Complaint. Lacking the most fundamental facts upon which to seek this Court's jurisdiction under any provision of the FCA, this Complaint should be dismissed under the standards of Federal Rules of Civil Procedure 8(a), 9(b) and 12(b)(6).

STATEMENT OF FACTS

A. The Parties

Stephen McMullen filed his Complaint on May 18, 2012 (Dkt. 1), and claims status as a relator under 31 U.S.C. § 3730(b)(2) (Compl. ¶ 1). On January 16, 2013, the United States declined to intervene and the Court ordered the Complaint unsealed and served upon Ascension. (Dkts. 13, 14.) McMullen asserts that he was a Registered Vascular Technologist employed by Baptist Hospital from September 2011 through at least May 2012. (Compl. ¶ 94.)[1] After this limited eight-month experience at a single hospital affiliated with a Health Ministry of Ascension, McMullen brings suit against Ascension and makes boilerplate allegations regarding more than 500 facilities nationwide.

This is not the only time McMullen has attempted to parlay limited employment experience into an expansive FCA suit concerning Medicare claims for noninvasive vascular diagnostic studies. On the same day he filed the Complaint, McMullen filed a virtually identical complaint against HCA Holdings, Inc., following a five-month period of employment at an

[1] Elsewhere in the Complaint, McMullen alleges that he was employed by Ascension Health in Nashville, Tennessee. (Compl. ¶ 6.) McMullen's allegation appears to be based upon his unfounded assertion – discussed in Section II.A. below – that Ascension "operates" the various facilities identified in the Complaint.

HCA-affiliated hospital in Hendersonville, Tennessee. (Dkt. 1, *United States ex rel. McMullen v. HCA Holdings, Inc.*, No. 3:12-cv-00502 (M.D. Tenn., filed May 18, 2012).) McMullen's complaint against HCA levels largely verbatim allegations against HCA (and over 270 HCA-affiliated facilities nationwide) as those McMullen makes against Ascension and its alleged affiliates in this matter. (*Compare id. with* Compl.)[2] And McMullen has previously brought similar claims. In September 2008, McMullen filed two *qui tam* FCA complaints in the United States District Court for the Western District of Tennessee.[3] After the United States declined to intervene in either case, McMullen voluntarily dismissed both.

Here McMullen alleges that Ascension "is a non-profit company that operates a network of hospitals and related healthcare facilities in the United States," including "more than 500 facilities in 20 states and the District of Columbia." (Compl. ¶¶ 24-25.) In law and in fact, Ascension, organized as a Missouri domestic non-profit corporation, is "a Catholic national health system consisting primarily of nonprofit corporations that own and operate local health care facilities, or Health Ministries, located in 21 of the United States and the District of

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[2] Indeed, Paragraph 30 of the Complaint provides direct evidence that McMullen cut and pasted from his complaint against HCA to draft the Complaint in this matter; the Complaint alleges "noninvasive vascular diagnostic studies billed to Medicare *by these HCA facilities* did not qualify for reimbursement under the Local Coverage Determination established by the Medicare Administration [sic] Contractor." (Compl. ¶ 30) (emphasis added).

[3] The first was brought against the Medicare Carrier for Tennessee, North Carolina, and Idaho, and alleged that the Carrier had breached its contract with the Centers for Medicare and Medicaid Services ("CMS") by processing and approving claims that did not comply with the Carrier's Local Coverage Determination ("LCD"). (*See* Ex. A, Dkt. 1, *United States ex rel. McMullen v. Cigna Gov't Servs., LLC*, No. 2:08-cv-02586-SHM-tmp (W.D. Tenn., filed Sept. 10, 2008).) The second was filed against a health clinic McMullen worked at for two months and alleged inappropriate billing in violation of a Carrier's LCD. (*See* Ex. B, Dkt. 1, *United States ex rel. McMullen v. The West Clinic, P.C.*, No. 2:08-cv-02587-BBD-cgc (W.D. Tenn., filed Sept. 10, 2008).) Unless otherwise indicated, exhibit references herein are to the exhibits attached to the Declaration of James Buck filed as Exhibit 1 to the Motion.

Columbia." (*See* Ex. D, Ascension Health Alliance Consolidated Financial Statements ("AHA Financial Stmt.") at 8; *see also generally* Ex. C, Ascension Health Articles of Amendment for Nonprofit Corporation ("Ascension Articles of Incorp.").) By law, these corporations, not Ascension, "own and operate local healthcare facilities, or Health Ministries[.]" (Ex. D, AHA Financial Stmt. at 8.)

B. The Complaint

Other than naming only Ascension as a defendant, the Complaint includes few facts regarding Ascension. The Complaint baldly and wrongly asserts without factual support that Ascension "operates" health care facilities nationwide. (*See*, *e.g.*, Compl. ¶¶ 2, 16-17, 24-26.) It alleges that very few of these facilities have laboratories accredited in vascular technology. (*Id.* ¶¶ 26-27, 96.) It alleges, without factual support, that Ascension "has presented false claims to Medicare for 'noninvasive vascular diagnostic studies' performed by non-accredited and/or non-certified technicians." (*Id.* ¶ 2.) And it "estimates that Ascension receives more than $50,000,000 per year in Medicare reimbursements for" such studies, (*id.* ¶ 92), and has done so "since at least 2008 and possibly since 2002" (*id.* ¶ 2). Notably, none of these allegations purport to be based upon McMullen's personal knowledge.

On that front, McMullen alleges that while he worked at Baptist Hospital, only five of the 13 technologists performing noninvasive vascular studies were certified as vascular technologists, and that noninvasive vascular diagnostic studies were not performed "by a physician or under the direct or general supervision of a physician credentialed in vascular technology." (*Id.* ¶¶ 95, 103-104.) Offering no additional facts, McMullen simply assumes that "a significant number of Medicare claims for noninvasive vascular diagnostic studies submitted by Baptist Hospital . . . did not qualify for Medicare reimbursement." (*Id.* ¶ 98.) McMullen further asserts "upon information and belief" that Medicare reimbursed Baptist Hospital over $350,000 per year since

at least 2005 for non-qualifying studies. (*Id.* ¶ 101.) Again, no facts are alleged against Ascension nor are facts alleged to support Baptist Hospital's receipt of such Medicare reimbursement.

The remainder of the Complaint is devoted to vague, repetitive allegations that noninvasive vascular diagnostic procedures performed at various facilities around the country (collectively the "Other Facilities") did not comply with the terms of LCDs established by Medicare administrative contractors and therefore did not qualify for Medicare reimbursement. (*Id.* ¶¶ 29-91.) Based on these non-specific and conclusory allegations, the Complaint alleges that each of the identified facilities "presented false claims to Medicare." (*Id.*)

This is the sum total of the Complaint. It does not specifically allege that any of the noninvasive vascular diagnostic studies purportedly performed at Baptist Hospital or any Other Facilities were performed on Medicare patients. It does not identify even a single claim allegedly submitted by any facility. And it does not allege facts showing any actual involvement in the billing or submission of claims by Ascension. To the contrary, the Complaint alleges without factual support that Baptist Hospital, not Ascension, submitted claims and received reimbursement. (*Id*. ¶ 98.)

C. The Medicare Program

McMullen's Complaint is based upon the alleged submission of "false" claims to Medicare purportedly in violation of "reimbursement criteria" that required noninvasive vascular diagnostic studies "be performed by a physician or technician certified in vascular technology or by an accredited laboratory." (Compl. ¶¶ 2, 29-91.) Medicare is a federal health insurance program available to most people over the age of 65 and certain people with disabilities or end-stage renal failure. *See* 42 U.S.C. § 1395c. The Medicare program is divided into several parts; relevant here are Parts A and B. Medicare Part A covers acute and long-term inpatient hospital

care, *see id.* §1395c (establishing coverage benefits under Medicare Part A), while Medicare Part B covers physician services as well as hospital outpatient and observation care, *see id.* § 1395k(a)(2)(B). Both Parts A and B cover medically necessary diagnostic tests, including noninvasive vascular diagnostic studies. *See* 42 U.S.C. § 1395x(b)(3) (defining "inpatient hospital services" to include "diagnostic or other therapeutic items or services furnished by the hospital"); 42 U.S.C. § 1395x(s)(2)(C) (defining "medical and other health services" to include "diagnostic services" "furnished to an individual as an outpatient by a hospital").

The Centers for Medicare and Medicaid Services ("CMS") is responsible for administering Medicare. CMS, in turn, contracts with private entities to receive and review claims, manage individual cases, interface with beneficiaries, collect coinsurance payments, assess the quality of care provided, and make payments to providers and suppliers for covered services. *See* 42 U.S.C. § 1395h; *id.* § 1395kk-1. Prior to mid-2007, private entities known as Fiscal Intermediaries ("FIs") administered Part A and "[m]ost Part B services from providers that furnish Part A services." Centers for Medicare and Medicaid Services, Medicare Claims Processing Manual ("MCPM"), Pub. 100-04, Chap. 1 § 10.2 (Rev. 1, Oct. 1, 2003), *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html. "Carriers" administered Part B claims by physicians, independent diagnostic testing facilities, and ambulatory surgical centers, among others. *Id.* § 10.1 (Rev. 1, Oct. 1, 2003). Beginning in mid-2007, CMS began consolidating the administration of Parts A and B into 15 regional A/B Medicare Administrative Contractors ("A/B MACs"), which have since assumed responsibility for coverage determinations and claims processing. *See* Medicare Prescription Drug, Improvement and Modernization Act of 2003, § 911, Pub. L. No. 108-173, 117 Stat. 2006 (2003), codified at 42 U.S.C. § 1395kk-1.

CMS is authorized to determine that payment may not be made by Medicare for an item or service. *See* 42 U.S.C. § 1395ff(a). CMS may make such determinations through a National Coverage Determination ("NCD"). *See id*. § 1395ff(f); *id*. § 1395y(a)(1)(A). Once issued, NCDs are "binding" on all Medicare claims contractors, 42 C.F.R. § 405.1060, and in the event of an appeal from a claim denial, NCDs are binding on those contractors and on administrative law judges ("ALJs"). *See* 42 U.S.C. § 1395ff(f).

Unless CMS has issued a related NCD, Medicare contractors are authorized to issue LCDs to establish their own coverage provisions regarding a good or service. *See* 42 U.S.C. § 1395ff(f)(2)(B); Centers for Medicare and Medicaid Services, Medicare Program Integrity Manual ("MPIM"), Pub No. 100-08, Chap. 13 § 13.1.3 (Rev. 443, Issued Dec. 14, 2012), *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html.[4] Such LCDs are neither agency regulations promulgated pursuant to the Administrative Procedures Act, 5 U.S.C. § 553 after notice and comment nor are they binding on ALJs considering appeals from claim denials for services furnished to Medicare beneficiaries. 42 C.F.R. § 405.1062(a); Review of NCDs and LCDs, 68 Fed. Reg. at 63,693. Significantly, McMullen only alleges that Ascension violated LCDs; no statute, regulation or NCD is alleged to have been violated.

[4] The term "local coverage determination" was created pursuant to section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA"), Pub. L. 106-554, 114 Stat. 2763A (2000), codified at 42 U.S.C. § 1395y(l). Prior to BIPA, Medicare contractors issued Local Medical Review Policies ("LMRPs"), which served largely the same purpose as LCDs. Medicare Program: Review of National Coverage Determinations and Local Coverage Determinations, 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003) ("Review of NCDs and LCDs").

ARGUMENT

I. APPLICABLE LEGAL STANDARDS

McMullen's Complaint alleges violations of 31 U.S.C. §§ 3729(a)(1), (a)(2), and (a)(3) by Ascension.[5] To sustain his claim under Section 3729(a)(1)(A), McMullen must plead with particularity that Ascension "knowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A) (2009). McMullen's claim under Section 3729(a)(1)(B) must allege with similar particularity that Ascension "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim." *Id*. § 3729(a)(1)(B). Finally, to plead a violation of Section 3729(a)(1)(C), McMullen must allege facts with particularity that Ascension conspired to commit a violation of another section of the FCA. *Id*. § 3729(a)(1)(C).

On its face, the Complaint fails these requirements, alleging, at most, that Ascension submitted claims not satisfying Medicare contractor local guidance that lacks conclusive legal effect. *United States ex rel. Hobbs v. Medquest Assocs., Inc.*, 711 F.3d 707, 716-17 (6th Cir. 2013) (holding that noncompliance with physician supervision requirements in a Medicare contractor's local coverage policy could not give rise to liability under the FCA).

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[5] The Fraud Enforcement and Recovery Act ("FERA"), Pub. L. No. 111-21, 123 Stat. 1617 (2009), renumbered the provisions at issue in this case as Section 3729(a)(1)(A), (a)(1)(B), and (a)(1)(C), respectively, and substantively amended their language. FERA generally applies to conduct occurring after May 20, 2009, and the amendment to Section 3729(a)(1)(B) specifically applies to civil actions or cases pending on or after June 7, 2008. *Id.* § 4(f)(1), 123 Stat. at 1626; *see also Sanders v. Allison Engine Co.*, 703 F.3d 930 (6th Cir. 2012). As the Complaint was filed in May 2012, we refer to the Sections of the FCA as amended by FERA, rather than as identified in the Complaint. We note, however, that to the extent the Complaint purports to allege FCA violations "since at least 2008 and possibly since 2002," (Compl. ¶ 2), conduct occurring prior to May 20, 2009 would be governed by the pre-FERA FCA provisions.

A. Federal Rule of Civil Procedure 9(b).

The "basis for a *qui tam* [FCA] action is *fraud* in the filing of claims against the government." *United States ex rel. Sanderson v. HCA*, 447 F.3d 873, 876 (6th Cir. 2006). Accordingly, "[c]omplaints alleging FCA violations must comply with Rule 9(b)'s requirement that fraud be pled with particularity." *United States ex rel. Chesbrough v. VPA, P.C.*, 655 F.3d 461, 466 (6th Cir. 2011). Rule 9(b) is intended "to provide defendants with a more specific form of notice as to the particulars of their alleged misconduct." *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 503 (6th Cir. 2007) (*Bledsoe II*). Indeed, Rule 9(b)'s heightened pleading standard serves three purposes: (1) "it ensures that defendants have the specific notice necessary to prepare a response"; (2) "it prevents prospective plaintiffs from engaging in fishing expeditions"; and (3) "it protects defendants' reputations against damage stemming from accusations of" wrongdoing. *Id.* at 503 n. 11; *see also United States ex rel. Marlar v. BWXT Y-12, L.L.C.*, 525 F.3d 439, 445 (6th Cir. 2008) ("'Rule 9(b) ensures that the relator's strong financial incentive to bring an FCA claim – the possibility of recovering between fifteen and thirty percent of a treble damages award – does not precipitate the filing of frivolous suits.'") (quoting *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 (11th Cir. 2006)). In general, to meet Rule 9(b)'s particularity requirement, the Complaint must allege the "who, what, when, where and how of the events at issue." *In re Rockefeller Ctr. Props., Inc.*, 311 F.3d 198, 217 (3d Cir. 2002).

B. Federal Rules of Civil Procedure 8(a)(2) and 12(b)(6).

A complaint is properly dismissed under Federal Rule of Civil Procedure 12(b)(6) when it fails to state a claim upon which relief can be granted. *Marlar*, 525 F.3d at 444. While less demanding than Rule 9(b), Rules 8(a)(2) and 12(b)(6) nevertheless require that a complaint articulate a "plausible" claim for relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 683 (2009). In

assessing the adequacy of a claim, courts must rely upon "judicial experience and common sense" in weighing competing inferences of lawful and unlawful conduct. *Id.* at 679 (dismissing claims for failure to allege intent where the more plausible inference was that the defendants intended to act lawfully). "[A] plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal quotation omitted). Further, on a motion to dismiss, courts "are not bound to accept as true a legal conclusion couched as a factual allegation." *Papasan v. Allain*, 478 U.S. 265, 286 (1986).

For the reasons detailed below, McMullen does not, and cannot, meet any of these legal pleading standards.

II. THE COMPLAINT FAILS TO PLEAD A VIOLATION OF 31 U.S.C. § 3729(a)(1)(A)

A. The Complaint Pleads No Basis For FCA Liability On The Part Of Ascension.

"[M]erely '[b]eing a parent corporation of a subsidiary that commits a FCA violation, without some degree of participation by the parent in the claims process, is not enough to support a claim against the parent for the subsidiary's FCA violation.'" *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 59-60 (D.D.C. 2007) (quoting *United States ex rel. Tillson v. Lockheed Martin Energy Sys., Inc.*, Nos. 5:00-CV-39 & 5:99-CV-170, 2004 WL 2403114, at *33 (W.D. Ky. Sept. 30, 2004)); *see also United States ex rel. West v. Ortho-McNeil Pharm., Inc.*, No. 03 C 8239, 2007 WL 2091185, at *5 (N.D. Ill. July 20, 2007) (dismissing FCA action against a corporate parent because the complaint did not set forth facts plausibly suggesting a cause of action). Accordingly, to state a claim against Ascension under Section 3729(a)(1)(A), the Complaint must allege facts that make it plausible that Ascension either presented or caused to be presented false or fraudulent claims for payment. It does neither.

The Complaint fails to allege any action or inaction on the part of Ascension. It offers only the factually unsupported assertion that Ascension "operates" more than 500 facilities nationwide. (Compl. ¶¶ 2, 16-17, 24-26; *see also, e.g., id.* ¶¶ 29, 32, 94.) While cast as an allegation of fact, this assertion lacks any factual support and should not be credited. The Court "need not accept as true legal conclusions or unwarranted factual inferences, and conclusory allegations or legal conclusions masquerading as factual allegations will not suffice." *Terry v. Tyson Farms, Inc.*, 604 F.3d 272, 275–76 (6th Cir. 2010) (citations and internal quotations omitted). Moreover, McMullen's unsupported allegation that Ascension "operates" healthcare facilities is belied by Ascension's legal status, of which the Court may take judicial notice for purposes of this Motion. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007) (when ruling on a Rule 12(b)(6) motion, courts consider the complaint as well as "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice"); *see also* Fed. R. Evid. 201(b) (courts may take judicial notice of "a fact that is not subject to reasonable dispute" because it is "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned").

As established by state public records of its corporate formation and authorization and its publicly available audited financial statements, Ascension is a Missouri domestic nonprofit corporation that serves as a holding company for a number of nonprofit corporations across the country. (*See* Ex. C, Ascension Articles of Incorp. at Art. II § 2.1.1 (explaining that Ascension is organized for, among other purposes, to "[s]erve as the parent corporation for Health Ministries sponsored by Ascension Health Ministries."); Ex. D, AHA Financial Stmt. at 8 (Ascension is "a Catholic national health system consisting primarily of nonprofit corporations . . . .").) Each of the non-profit corporations affiliated with Ascension are domiciled in the states in which they are

located; such corporations primarily own and/or operate local healthcare facilities. For example, Seton Corporation d/b/a Baptist Hospital is owned and/or operated by Saint Thomas Health, a Tennessee domestic nonprofit corporation. (*See* Ex. J, Amended Charter of Seton Corporation at 3 (St. Thomas Baptist Health Corporation is the sole corporate member of Seton Corporation); Ex. K, Seton Corp. Application for Assumed Corporate Name at ¶ 4 (Seton Corporation transacts business as Baptist Hospital); Ex. I, Amended Charter of St. Thomas Baptist Health Corporation at 3 (Ascension Health is the sole corporate member of St. Thomas Baptist Health Corporation.) Baptist Hospital – not Ascension – is also accredited by The Joint Commission and licensed by the State of Tennessee as a hospital. (Ex. E., Joint Commission Accreditation Quality Report for Baptist Hospital; Ex. H, Baptist License Verification.)

The Court may take judicial notice of these publicly filed and publicly available documents. *See Arvest Bank v. Byrd*, 814 F. Supp. 2d 775, 787 n.4 (W.D. Tenn. 2011) ("The Court takes judicial notice that Arvest is listed on the Arkansas Secretary of State's website as an Arkansas bank with its principal address in Arkansas.") (citations omitted); *E.E.O.C. v. Jeff Wyler Eastgate, Inc.*, No. 1:03CV662, 2006 WL 2785774, at *2-3 (S.D. Ohio Jan. 9, 2006) ("the Court may take judicial notice of the public records. . . [which] are official documents from the Ohio, Kentucky, and Indiana Secretary of State and therefore, possess the requisite level of reliability.").

McMullen offers no credible facts to support his conclusory allegations that Ascension "presented false claims to Medicare" (Compl. ¶ 2; *see also id.* ¶ 109-12); rather, he is silent as to how Ascension allegedly did so. His suppositions are not only unsupported by facts, but also are legally impossible, given Ascension's separate corporate structure and lack of Medicare "provider" status. Under the terms of the Social Security Act and its implementing regulations,

"providers of services" must apply to participate in the Medicare program, 42 C.F.R. § 424.510, and must demonstrate that they are licensed pursuant to the laws of the state in which they are located, *id.* § 482.11. If a provider is deemed to meet the various conditions of participation in Medicare, it may enter a Medicare provider agreement. *Id.* §§ 489.2, 489.10. Once enrolled in Medicare, a provider has billing privileges, *id.* § 424.505; to actually submit bills, providers must obtain a unique "National Provider Identifier" ("NPI"), which must be included on all Medicare claims, *id.* § 424.506.

The Complaint does not allege that Ascension is licensed to provide health care services under the laws of any state, has enrolled in Medicare or entered a Medicare provider agreement, or has an NPI permitting Ascension to submit claims to Medicare. Nor could the Complaint truthfully do so. Indeed, the Complaint itself appears to recognize this reality by repeatedly alleging only that Baptist Hospital and the Other Facilities "have billed Medicare for noninvasive vascular diagnostic studies" and "have presented false claims to Medicare." (*See, e.g.*, Compl. ¶¶ 30-31, 33-34; *see also id.* ¶ 98 ("a significant number of Medicare claims for noninvasive vascular diagnostic studies submitted *by Baptist Hospital* . . . did not qualify for Medicare reimbursement") (emphasis added).)

The Complaint likewise is silent as to how Ascension allegedly "caused" any facilities to submit false claims. Fundamentally, the Complaint fails to allege with requisite particularity that any facility actually submitted a false or fraudulent claim for payment by the Medicare program, much less how Ascension caused such a fraudulent submission. The Complaint offers no facts connecting Ascension to any such claims and no facts showing Ascension caused such claims to be submitted. Merely being a corporate "parent" is insufficient. *Hockett*, 498 F. Supp. 2d at 59-60. Instead, an FCA claim "requires some affirmative participation or action by [Ascension] that

furthers the unlawful objective." *See United States ex rel. Lisitza v. Par Pharm. Cos., Inc.*, No. 06-C-06131, 2013 WL 870623, at *5 (N.D. Ill. Mar. 7, 2013) (dismissing FCA complaint against companies where allegations pertaining to common parentage and corporate overlap were "too general to provide factual support for the conclusory statement that [the companies] controlled or directed [a third company] with respect to the fraudulent scheme"). Indeed, even "knowledge of the submission of claims and knowledge of the falsity of those claims is insufficient to establish liability under the FCA" absent "some sort of affirmative action" that "causes the presentment of a false claim." *United States ex rel. Sikkenga v. Regence BlueCross BlueShield of Utah*, 472 F.3d 702, 714 (10th Cir. 2006). Here, the Complaint alleges no facts suggesting that Ascension played any role in the alleged submission of false claims, and therefore offers no factual predicate for FCA liability on the part of Ascension.

B. The Complaint Must Be Dismissed For Failing To Plead Fraud With The Particularity Required By Rule 9(b).

To plead an FCA violation with requisite particularity, a plaintiff must allege "(1) 'the time, place, and content of the alleged misrepresentation,' (2) 'the fraudulent scheme,' (3) the defendant's fraudulent intent, and (4) the resulting injury." *Chesbrough*, 655 F.3d at 467 (quoting *Bledsoe II*, 501 F.3d at 504). The Complaint fails to plead any misrepresentation and fails to plead a "fraudulent scheme" with particularity and therefore must be dismissed.

1. The Complaint Does Not Identify a Single Claim Presented for Payment.

Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). In the context of an FCA case, the "circumstances constituting fraud" "must include an averment that a false or fraudulent claim for payment or approval has been submitted to the government." *Bledsoe II*, 501 F.3d at 504; *see also Chesbrough*, 655 F.3d at 467 (explaining the alleged

"misrepresentation" is the presentment of a false claim for payment by the Federal government). "[P]leading an actual false claim with particularity is an indispensable element of a complaint that alleges a FCA violation in compliance with Rule 9(b)." *Bledsoe II*, 501 F.3d at 504. Indeed, "the fraudulent claim is 'the *sine qua non* of a False Claims Act violation.'" *Sanderson*, 447 F.3d at 878 (quoting *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002)).

McMullen's Complaint altogether fails to allege "which specific false claims constitute a violation of the FCA." *Bledsoe II*, 501 F.3d at 505. With respect to Baptist Hospital – the only facility of which McMullen allegedly has personal knowledge – he offers one specific factual allegation: that Baptist Hospital employed 5 certified and 8 non-certified vascular technologists during the 8-month period McMullen worked at the hospital. (Compl. ¶ 95.) From this, and this alone, McMullen concludes that "[a]pproximately 42% of noninvasive vascular diagnostic studies performed at Baptist Hospital were not performed by or under the supervision of a qualified physician, a credentialed vascular technologist, or at a laboratory accredited in vascular technology." (Compl. ¶ 98.) This is supposition, not fact. *See Terry*, 604 F.3d at 275-76 ("unwarranted factual inferences" need not be credited on a motion to dismiss). McMullen does not allege personal knowledge of which technologists performed particular noninvasive vascular diagnostic studies, even though he alleges that 5 of the technologists were certified. He does not identify which particular studies allegedly were not performed under physician supervision.[6] And he does not demonstrate that laboratories were even required to be accredited. He simply

[6] In the context of the relevant Medicare regulations, "under the supervision" of a physician may mean simply that "the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure." 42 C.F.R. § 410.32. McMullen certainly does not allege facts to demonstrate this was not the case for 42% of the noninvasive vascular diagnostic studies performed at Baptist Hospital.

supposes that studies did not meet one of the three legally non-binding LCD criteria he believes to be relevant.

More importantly, even if McMullen's conjecture were true, it is of no consequence unless Ascension actually presented claims for studies for Medicare payment knowing that they did not qualify for reimbursement. *Sanderson*, 447 F.3d at 877 (citing *Clausen*, 290 F.3d at 1311 ("[T]he False Claims Act does not create liability . . . unless . . . the provider knowingly asks the Government to pay amounts it does not owe.")). While McMullen identifies the allegedly non-certified technologists he asserts performed noninvasive vascular diagnostic studies at Baptist Hospital (Compl. ¶ 104), he does not allege that those studies were performed on Medicare patients or that claims for such studies were submitted to Medicare. He offers only generalized speculation that "a significant number of Medicare claims for noninvasive vascular diagnostic studies submitted by Baptist Hospital to Cigna Government Services and/or Wisconsin Physicians Service Insurance Company, did not qualify for Medicare reimbursement." (Compl. ¶ 98.) But, to conclude from this bald assertion "that a claim was [actually] presented requires a series of assumptions." *Chesbrough*, 655 F.3d at 472. At the most basic level, "one must assume that the tests were performed on Medicare . . . patients and could therefore have been billed to the government." *Id.* That such an assumption is required to accept McMullen's allegations as true demonstrates that the Complaint fails to meet the requirements of Rule 9(b).

The Complaint's deficiencies are even more glaring with regard to the "Other Facilities." McMullen offers only the repetitious verbatim allegation that that the facilities "billed Medicare for noninvasive vascular diagnostic studies" that "did not qualify for reimbursement under the Local Coverage Determination established by the Medicare Administrator Contractor." (*See*, *e.g.*, Compl. ¶¶ 30-31, 33-34.) These undifferentiated general allegations are made as to large

groups of facilities organized by state and therefore inherently fail to identify the "'time, place, and content of [any] alleged misrepresentation.'" *United States ex rel. Bledsoe v. Comm. Health Sys., Inc.*, 342 F.3d 634, 643 (6th Cir. 2003) ("*Bledsoe I*") (quoting *Coffey v. Foamex L.P.*, 2 F.3d 157, 161-62 (6th Cir. 1993)). McMullen's broad generalized allegations of fraudulent claims are more legally insufficient conjecture. *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 457 (4th Cir. 2013) ("[W]hen a defendant's actions, as alleged and as reasonably inferred from the allegations, *could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment.") (emphasis in original).

And here the allegations are pled merely on "information and belief," unsupported by any facts. "'While fraud may be pled on information and belief when the facts relating to the alleged fraud are peculiarly within the perpetrator's knowledge, the plaintiff must still set forth the factual basis for his belief.'" *Bledsoe II*, 501 F.3d at 512 (quoting *United States ex rel. Williams v. Bell Helicopter Textron, Inc.*, 417 F.3d 450, 454 (5th Cir. 2005)). McMullen "does not provide any information upon which his belief is based." *Bledsoe II*, 501 F.3d at 512. His "belief" that claims may have been submitted simply is not sufficient. *Takeda*, 707 F.3d at 456-57 ("[T]he particularity requirement of Rule 9(b) 'does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government.'") (quoting *Clausen*, 290 F.3d at 1311).

Finally, McMullen offers no details that might raise his allegations beyond the realm of assumption and speculation, such as "dates on which the purportedly false [claims] were

submitted, . . . who submitted the purportedly false [claims], . . . [or] any other 'specific information about the [claims] allegedly submitted.'" *Marlar*, 525 F.3d at 446 (quoting *Bledsoe II*, 501 F.3d at 512-13). Instead, he attempts to distract by offering "estimates" (Compl. ¶ 92) and conjecture pled "upon information and belief" (*id.* ¶ 101) regarding Medicare reimbursements purportedly received by Baptist Hospital and Ascension. But, again, he offers no factual basis to support his belief, and speculation piled upon speculation does not satisfy Rule 9(b). *Sanderson*, 447 F.3d at 878 (the "information and belief" "exception must not be mistaken for license to base claims of fraud on speculation and conclusory allegations") (internal quotation omitted). Accordingly, McMullen's Complaint must be dismissed, as it offers no grounds for believing that Ascension, Baptist Hospital or any Other Facility actually submitted claims to Medicare for noninvasive vascular diagnostic studies.

2. The Complaint Does Not Plead a "Fraudulent Scheme" With Particularity.

Under Rule 9(b), McMullen must also allege with particularity facts to support the existence of a "fraudulent scheme," i.e., that any claims presented were false and made with the requisite scienter. *Chesbrough*, 655 F.3d at 467 (citing *Bledsoe II*, 501 F.3d at 504). "It is only those claims for money or property to which a defendant is not entitled that are 'false' for purposes of the False Claims Act." *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 674-75 (5th Cir. 2003) (en banc). "[T]he requisite intent is the knowing presentation of what is known to be false, as opposed to negligence or innocent mistake." *Mikes v. Straus*, 274 F.3d 687, 703 (2d Cir. 2001); *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999) ("violations of [federal] regulations are not fraud unless the violator knowingly lies to the government about them").

While McMullen broadly alleges that noninvasive vascular diagnostic studies performed at the Other Facilities "did not qualify for reimbursement under the Local Coverage Determination established by the Medicare Administrator [sic] Contractor," he does not identify which LCDs purportedly applied to which facilities, at which points in time. (*See, e.g.*, Compl. ¶¶ 30, 33; *see also id.* ¶ 98 (alleging that claims for studies submitted by Baptist Hospital to Cigna Government Services and/or Wisconsin Physicians Service Insurance Company, did not qualify for reimbursement," without reference to any LCD.) Indeed, McMullen does not even allege facts to suggest that any specific LCDs were effective or binding on any facility during the time period at issue. (*See id.* ¶¶ 17-22 (asserting "[u]pon information and belief" that LCDs restricting reimbursement for noninvasive vascular diagnostic studies "*may* have been applicable since at least 2005") (emphasis added).) And the Complaint is also wholly devoid of any allegations that Baptist Hospital or any Other Facility knowingly lied about or misrepresented compliance with any particular LCD. McMullen's vague and conclusory allegations do not plead a "fraudulent scheme" at all, let alone with the particularity required by Rule 9(b). His Complaint must be dismissed.

B. The Complaint Should Be Dismissed Pursuant To Rule 12(b)(6) Because It Fails To Allege The "Knowing" Submission Of A False Or Fraudulent Claim.

The terms "false" and "fraudulent" as used in the FCA "require a defendant to have aimed to extract from the government 'money the government otherwise would not have paid.'" *Chesbrough*, 655 F.3d at 467 (quoting *Mikes*, 274 F.3d at 696). "At a minimum, the FCA requires proof of an objective falsehood." *United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 F. App'x 980, 982 (10th Cir. 2009).

Claims must be either "factually false" or "legally false" to be actionable under the FCA. *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir.

2008). Claims are "factually false" if they provide an "'incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *Id.* (quoting *Mikes*, 274 F.3d at 697); *accord United States ex rel. Siewick v. Jamieson Sci. & Eng'g, Inc.*, 214 F.3d 1372, 1378 (D.C. Cir. 2000) (noting that the FCA applies only to claims that one "could reasonably classify as true or false"). McMullen does not allege that Ascension or any facility billed Medicare for noninvasive vascular diagnostic tests that were not actually performed. Thus, he does not allege the submission of a factually false claim.

Claims may be legally false under an express "false certification" theory when the claimant knowingly and "expressly states that [the claim] complies with a particular statute, regulation, or contractual term that is a prerequisite for payment[.]" *Chesbrough*, 655 F.3d at 467. McMullen, however, does not allege that Ascension or any facility expressly certified compliance with any "statue, regulation, or contractual term" in connection with any claim.

The Sixth Circuit has also "adopted the 'implied certification' theory of liability, holding that 'liability can attach if the claimant violates its continuing duty to comply with the regulations on which payment is conditioned.'" *Chesbrough*, 655 F.3d at 468 (quoting *United States ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409, 415 (6th Cir. 2002)). Even under the implied certification theory, however, "a relator cannot merely allege that a defendant violated a standard—he or she must allege that compliance with the standard was required to obtain payment." *Chesbrough*, 655 F.3d at 468.

As a result, to the extent McMullen is attempting to assert an "implied certification" theory based upon alleged noncompliance with various LCDs, he fails again. While McMullen alleges in conclusory terms that LCDs established "criteria for Medicaid reimbursement for noninvasive vascular diagnostic studies" (Compl. ¶ 17), the Complaint does not identify any

provision of any LCD conditioning payment on compliance with physician credentialing, technologist certification or lab accreditation criteria.[7] At most, these quality of care provisions in LCD excerpts quoted in the Complaint establish "conditions of participation" which are not actionable under a false certification theory. *Hobbs*, 711 F.3d at 714 ("[A] false-certification theory only applies where the underlying regulation is a 'condition of payment,' meaning that the government would not have paid the claim had it known the provider was not in compliance."). In *Hobbs*, the Sixth Circuit reversed the lower court's finding of FCA liability for alleged noncompliance with provisions in a LMRP, indistinguishable from the LCDs in issue here, that required certain procedures at independent diagnostic testing facilities be supervised by board-certified radiologists because the LMRP established only "conditions of participation" that did not displace the coverage criteria in applicable Medicare statutes and regulations. *Hobbs*, 711 F.3d at 716-17; *see also United States v. Prabhu*, 442 F. Supp. 2d 1008, 1032-33 (D. Nev. 2006) (holding that claims that did not comply with a Medicare contractor's LMRP could not be false as a matter of law because, unlike applicable statutes and regulations, LMRPs do not establish "controlling" standards).

LCDs are simply "administrative and educational tools" published by private Medicare administrative contractors "to assist providers in submitting correct claims for payment." *See* Review of NCDs and LCDs, 68 Fed. Reg. at 63,693; MPIM, Chap. 13 § 13.1.3. Unlike statutes, regulations, or even NCDs, LCDs are not binding during the administrative appeals process or on a federal court reviewing a coverage determination for services provided to a Medicare

[7] Although the Complaint represents that applicable LCDs are attached as Exhibit A (Compl. ¶ 17), McMullen provided no actual LCDs. Instead, the Complaint attaches excerpts from LCDs printed from the website of the Intersocietal Accreditation Commission for Vascular Testing. (*See* Compl. at Ex. A.)

beneficiary. *See* 42 C.F.R. § 405.1062; *see also Willowood of Great Barrington, Inc. v. Sebelius*, 638 F. Supp. 2d 98, 106 (D. Mass. 2009) (LCDs "are not binding during the administrative process or before this court"). Indeed, "an ALJ may rule that Medicare payment is due on a particular item or service received by a beneficiary . . . *even if the contractor's LMRP or LCD clearly prohibits payment for the particular service*." Review of NCDs and LCDs, 68 Fed. Reg. at 63,693 (emphasis added). LCDs also "do not address fraud" and CMS has admonished Medicare contractors to refrain from using the terms "fraud" or "fraudulent" when developing LCDs. MPIM Chap. 13 § 13.1.3.

Finally, even if the LCD provisions relied upon in the Complaint did establish conditions of payment, McMullen has alleged no facts – only speculation – that any entity submitted claims in violation of such conditions. The few facts in the Complaint possibly gleaned during McMullen's employment at Baptist Hospital demonstrate his lack of knowledge concerning Medicare billing and the implausibility of the Complaint's generalized allegations. As discussed above, McMullen broadly supposes that "a significant number of Medicare claims for noninvasive vascular diagnostic studies submitted by Baptist Hospital to Cigna Government Services and/or Wisconsin Physicians Service Insurance Company, did not qualify for Medicare reimbursement." (Compl. ¶ 98.) Despite these allegations, Baptist Hospital's Medicare claims were not subject to any LCDs or LMRPs issued by those entities. During the time in question, Cigna was a Medicare Carrier for Tennessee, not the FI. (*See* Exhibit F, CMS A/B MAC Fact Sheet Jurisdiction 10 ("CMS Fact Sheet").) And before the creation of A/B MACs, hospitals, like Baptist, submitted Medicare claims for both Part A and B services to FIs, not Carriers like Cigna. *See* MCPM Chap. 1 § 10.2.

The FI that actually administered Baptist Hospital's Medicare claims for much of the relevant period was Riverbend Government Benefits Administrator ("Riverbend") – not Wisconsin Physician Service Insurance Company ("WPS") as implied in the Complaint. (*See* Exhibit F, CMS Fact Sheet.)[8] Riverbend's LCD applicable to services provided by Baptist Hospital between December 27, 1996 and August 2, 2009, did not establish any technologist credentialing, physician supervision, or lab accreditation criteria as either a condition of payment or a condition of participation. (*See* Ex. G, Riverbend LCD L1352.)[9]

In sum, the Complaint utterly fails to allege that Ascension or any affiliated entity submitted a "false or fraudulent claim" and fails to state a claim upon which relief can be granted.

III. THE COMPLAINT FAILS TO PLEAD A VIOLATION OF 31 U.S.C. § 3729(a)(1)(B) BECAUSE IT DOES NOT IDENTIFY A FALSE RECORD OR STATEMENT

Section 3729(a)(1)(B) of the FCA prohibits "knowingly [making, using, or causing] to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B)(2009). To plead a claim under Section 3729(a)(1)(B) with the particularity required by Rule 9(b), McMullen "must provide sufficient details regarding the time, place and content of [the] alleged false statements, [the] claim for payment . . . , and the manner in which the false statements" were material to a false or fraudulent claim. *United States ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 505 (6th Cir. 2008) (stating pleading requirements under

[8] McMullen does not expressly allege that WPS was the Medicare FI for Baptist Hospital, nor could he accurately do so.

[9] The Court may take judicial notice of these facts, all of which are publicly known and capable of accurate and ready determination though governmental information sources. Fed. R. Evid. 201(b); *City of Monroe Emps. Ret. Sys. v. Bridgestone Corp.*, 399 F.3d 651, 655 n.1 (6th Cir. 2005) (taking judicial notice of information posted on the website of the National Association of Securities Dealers, Inc.).

pre-FERA Section 3729(a)(2)). McMullen's Complaint does none of these things.

The full extent of McMullen's allegations regarding Section 3729(a)(1)(B) is his formulaic assertion that Ascension "submitted or caused to be submitted and presented or caused to be presented the false and/or fraudulent claims or false records for payment or approval." (Compl. ¶ 111) (emphasis added). This garbled statement does not identify any "false record or statement," nor is one identified elsewhere in the Complaint. It certainly does not provide "details regarding the time, place and content" of any false statement or any false or fraudulent claims. *SNAPP*, 532 F.3d at 505. Accordingly, McMullen's claim under Section 3729(a)(1)(B) must be dismissed.

IV. THE COMPLAINT FAILS TO PLEAD A VIOLATION OF 31 U.S.C. § 3729(a)(1)(C) BECAUSE IT DOES NOT IDENTIFY THE ELEMENTS OF A CONSPIRACY

Finally, to plead a violation Section 3729(a)(1)(C), a plaintiff must allege with particularity a conspiracy "to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)" of Section 3729(a)(1). 31 U.S.C. § 3729(a)(1)(C); *see also Marlar*, 525 F.3d at 445 (Rule 9(b)'s heightened pleading standard applies to claims under pre-FERA Section 3729(a)(3)). "The essence of a conspiracy under the Act is an agreement between two or more persons to commit fraud." *United States ex rel. Piacentile v. Sanofi Synthelbo, Inc.*, No. 05-2927, 2010 WL 5466043 at *9 (D.N.J. Dec. 30, 2010). "Under Rule 9(b), general allegations of a conspiracy, without supporting facts to show when, where or how the alleged conspiracy occurred, amount to only a legal conclusion and are insufficient to state a cause of action." *United States ex rel. Dennis v. Health Mgmt. Assocs., Inc.*, No. 3:09-cv-00484, 2013 WL 146048, at *17 (M.D. Tenn. Jan. 14, 2013). To establish a conspiracy under Section 3729(a)(1)(C), McMullen "must show (1) that there was a single plan to [violate a Section of the FCA], (2) that the alleged coconspirators shared in the general conspiratorial objective . . . , and (3) that one or more conspirators

performed an overt act in furtherance of the conspiracy . . . ." *United States ex rel. Judd v. Maloy*, No. 3:03-CV-241, 2006 WL 2583318, at *9 (S.D. Ohio, Sept. 6, 2006).

Although McMullen's "Claim for Relief" is framed as one for "Violation of 31 § [sic] U.S.C. 3729(a)(1), (a)(2), (a)(3)," he offers no allegations whatsoever regarding any purported conspiracy. He does not identify any "conspirators," let alone identify an alleged plan to violate the FCA or overt acts taken in furtherance of such a plan. He therefore cannot pursue a cause of action under Section 3729(a)(1)(C).

CONCLUSION

For all the foregoing reasons, Defendants respectfully request that the Court grant Defendants' Motion to Dismiss Relator's Complaint. Because the Complaint's deficiencies cannot be cured by amendment, the Complaint should be dismissed with prejudice.

Respectfully submitted,

Dated: June 18, 2013

/s/ Gregory M. Luce

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on June 18, 2013 the foregoing was electronically filed with the Clerk of Court using the CM/ECF system, which automatically serves notification of such filing to the following counsel of record:

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